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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,536	03/11/2004	Leah E. Appel	PC10270B	7842

28523 7590 06/14/2007

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,536	APPEL ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-52,55-57 and 59-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52,55-57 and 59-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/17/07 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49, 52, 55-57 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. WO 95/30422 A1, in view of Kigoshi US 6,254,889.

Curatolo discloses a bi-layer core comprising a drug layer, and a layer containing an expandable hydrogel with an osmotic agent (page 20, last paragraph; and example 18). The core is coated with a water permeable membrane containing one or more exit passageways (ID). Osmagent includes sugars or salts such as sucrose, mannitol or sodium chloride (page 21, lines 17-18). Hydrogel includes sodium carboxymethyl cellulose,

poly(ethylene oxide), poly(acrylic acid), sodium(poly-acrylate) and other high molecular weight hydrophilic materials (ID). Drug includes azithromycin (antibiotic) (ID). Curatolo further teaches the drug layer also comprises hydroxypropylmethylcelluose (HPMC), or polyvinylpyrrolidone (PVP) (page 21, 3rd paragraph).

Curatolo does not explicitly teach the claimed dispersion polymer in the core.

Kigoshi teaches a solid dispersion dosage form of a slightly soluble drug comprising dispersing an amorphous drug in a dispersion polymer including hydroxypropylmethyl cellulose acetate succinate (see abstract; and column 3, lines 18-33). The dispersing solution is sprayed onto an absorbent carrier to obtain a drug core. The core is than mixed with excipient, and made into dosage form (column 4, lines 39-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the drug core of Curatolo using the solid dispersion of an amorphous drug in view of the teaching of Kigoshi, because Kigoshi teaches slightly soluble drugs have high crystallinity and low bioavailability, because Kigoshi teaches improving the solubility and bioavailability of slightly soluble drugs by dispersing slightly soluble drug in a polymer to form a solid dispersion, because Curatolo teaches the use of poorly soluble drugs, because Curatolo teaches the desirability to prepare a sustained release dosage form using dispersion polymer in the drug layer,

and because Curatolo teaches polymers in the drug layer including PVP, HPMC, and other pharmaceutically-acceptable carrier.

Claims 49-52, 55-57 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. WO 95/30422, in view of Kerc et al. WO 96/36318.

Curatolo is relied upon for the reason stated above. Curatolo does not expressly teach drug in amorphous form.

Kerc discloses a pharmaceutical composition comprising a core, and a coating surrounding the core (page 4, 1st and 2nd paragraphs). The core comprises an amorphous drug dispersed in a polymer such as polyvinyl pyrrolidone and hydroxypropylmethyl cellulose with a viscosity from 3-1500 mPa.s (page 7; and example 1). The core is further mixed with excipients including cellulose ethers, glidant, filler, and lubricant (osmotic agent and osmotically effective solute) (page 8, 2nd-3rd paragraph; page 9, 1st-2nd paragraph; and page 10, last paragraph through page 11, 2nd-3rd paragraph). The core is then coated with a film coating (page 9, paragraph 3 through page 10; page 11, paragraphs 2-3). Drug includes antibiotics, antihypertensives, antiparkinson, hypnotic, and those disclosed in page 5, 4th paragraph. The composition can be prepared in granule (multiparticulate) form, the granule can then be compressed into tablet, and the tablet is coated with a film (page 11; and examples). Thus, it would have been obvious to one of ordinary skill in the art to modify the morphology of the drug taught by Curatolo to use drug

in amorphous form in view of the teaching of Kerc, because Kerc teaches amorphous drug exhibits constant and controlled release rate, independent from its polymorphous forms, crystallinity, particle size and specific surface area (page 4, 2nd paragraph), because Kerc teaches a composition suitable for a wide variety of drugs including antibiotic agent, and because Curatolo teaches the desirability of obtaining a useful controlled release dosage form of an antibiotic agent.

It is noted that the cited references do not teach the dosage form provides an AUC in a use environment that is at least 1.25 fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug, as claimed in claims 60 and 61. However, absent of evident to the contrary, it is the position of the examiner that the osmotic device taught by Curatolo in view of Kigoshi or Kerc, would provide a similar AUC because references teach the use of a similar dosage structure suitable for the claimed active agent, namely, a controlled release dosage form with bi-layer core coating with a water-permeable coating with at least one exit passageway.

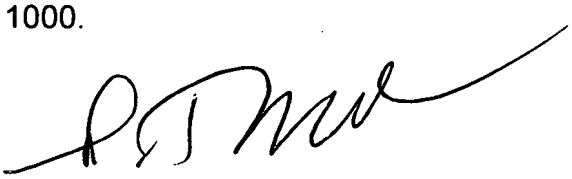
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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AU 1615